DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 11-5-98
Publication Date 11-6
Certifier LBoulis

Food and Drug Administration

[FDA 225–98–8002]

# Memorandum of Understanding Between the Food and Drug Administration and the Office of the United States Trade Representative

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

---

**SUMMARY:** The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Office of the United States Trade Representative. The purpose of the MOU is to set forth the understandings and procedures which will guide their cooperative execution of the Joint Committee provisions of the Agreement on Mutual Recognition between the United States of America and the European Community.

**DATES:** The MOU became effective May 1, 1998.

**FOR FURTHER INFORMATION CONTACT:** Merton Smith, Office of International Affairs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c), which states that all written agreements and understanding between FDA and other departments, agencies, and organizations shall be published in the **Federal Register** (except those between FDA and State and local government agencies that are cooperative work-sharing agreements), the agency is publishing notice of this MOU.

Dated: September 28, 1998

September 28, 1998

William K. Hubbard
Associate Commissioner for Policy Coordination

[INSERT MOU HERE]

[FR Doc. 98–???? Filed ??–??–98; 8:45 am]

**BILLING CODE 4160–01–F**

225-98-8002

# MEMORANDUM OF UNDERSTANDING REGARDING THE JOINT COMMITTEE UNDER THE FRAMEWORK AGREEMENT ON MUTUAL RECOGNITION BETWEEN THE UNITED STATES OF AMERICA AND THE EUROPEAN COMMUNITY

The United States and the European Community have negotiated an Agreement on Mutual Recognition (the "Agreement"), consisting of an umbrella agreement and several sectoral annexes. Products covered in the Sectoral Annex for Pharmaceutical Good Manufacturing Practices ("GMPs") and the Sectoral Annex on Medical Devices are regulated by the United States Food and Drug Administration ("FDA").

The umbrella agreement establishes a Joint Committee responsible for the effective functioning of the Agreement as a whole, and the sectoral annexes on pharmaceutical GMPs and medical devices establish separate Joint Sectoral Committees responsible for the operation of the respective sectoral annexes. Under the Agreement, issues discussed in the Joint Sectoral Committees regarding, among other things, equivalence determinations of authorities or conformity assessment bodies, may be referred to the Joint Committee.

In recognition of the relationship between the Agreement and FDA's core domestic statutory and regulatory responsibilities relating to protection of health and safety under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and related statutes, execution of which is committed to FDA, and in light of the United States Trade Representative's (USTR) role under section 141 of the Trade Act of 1974 and Reorganization Plan #3 of 1979, FDA and USTR set forth in this Memorandum of Understanding ("MOU") the understandings and procedures which will guide their cooperative execution of the Joint Committee provisions of the Agreement.

Upon establishment of the Joint Committee pursuant to Article 14 of the Agreement, USTR shall notify FDA of matters to be considered by the Joint Committee. Subject to arrangements with other agencies covered by the Agreement, USTR normally shall speak for and vote on behalf of the United States in the Joint Committee. A representative of FDA shall speak for and vote on behalf of the United States on any matter pertaining to FDA's statutory or regulatory authority. The representative of FDA shall also represent the USG on such matters in any other committees or bodies with similar functions established under the Agreement or its annexes.

Susan G. Esserman
General Counsel
United States Trade Representative

Date: April 16, 1998
April 16, 1998

Michael A. Friedman, M.D.
Lead Deputy Commissioner,
United States Food and Drug Administration

Date: 5/1/98
May 1, 1998